CTMS Structured Protocol Representation SIG Teleconference Meeting Notes

Meeting Date	Tuesday, August 3, 2004 1-2 PM EDT
Attendees:	**Working group coordinator**: Scott Finley (Booz Allen Hamilton) Harshawardhan Bal (Booz Allen Hamilton) **Participants:**

Name	Email	Organization
Doug Fridsma (SIG Lead)	**fridsma@cbmi.pitt.edu**	**UPMC**
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Agenda

1. Introductions

2. Review Face to Face to meeting
   a. PowerPoint presentation with Doug Fridsma's notes
   b. Vision statement
   c. Scope of work
   d. Statements of work (proposed)
   e. Review comments

3. SIG deliverables (discussion)
   a. White paper on current status of structured protocol representations
   b. White paper on design considerations/desiderata
   c. White paper on use case – clinical trial registration and summary 4

4. Additional discussion items

5. Next meeting: August 17th 1:00 EDT

General discussion points raised by participants:

There was a concern that it may be difficult to develop a "generic" protocol authoring tool that could uniformly be applied to the widely diverse requirements of different cancer centers and clinical trial sites or to the

	different types of clinical trials (Treatment, Prevention, Screening and early detection, Diagnostic, Genetics and Quality-of-life). The relationship of structured protocol representation to other aspects of CTMS was discussed and it was felt that structured protocol representation could have an impact on other areas such as Adverse Events reporting. Input from other SIGs was therefore felt to be valuable to the Structured Protocol Representation SIG. The level to which structured protocol representation should have direct links to the CDEs or be mapped to the caDSR was debated. It was felt that a level of baseline mapping to CDEs might be needed right at inception, especially with respect to attaining consensus on important data elements such as what constitutes a Phase I/II or III trial. This is consistent with the fact that centers conducting (certain types of) trials overseen by NCI are required to transmit data using CDEs and therefore a level of CDE readiness will be beneficial. In addition, it would leverage the CDEs that are already available for therapeutic phase I/II/III cancer trials (and prevention trials). A similar effort (to map data to CDEs to disambiguate clinical trial phases) was being used by CDISC. It was felt that the goal to achieve deep CDE mapping across all stages of the clinical trial life cycle may be difficult to achieve at the outset due to several reasons including the fact that CDEs may not be available or be under development for specific purposes (such as patient eligibility criteria and others). Instead, it may be necessary to first define the scope and the requirements for the process/software and then prioritize areas for CDE mapping.
Action items:	1. Write white papers on clinical trials on areas covering current status of structured protocol representations, design considerations/desiderata, use case – clinical trial registration and summary 4 2. Define the scope for the Structured Protocol Representation module and prioritize areas for CDE mapping